

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:3917
ANSWERED ON:20.04.2005
SALE OF SUB-STANDARD DRUGS
Gadhavi Shri Pushpdan Shambhudan

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether registration system for the imported drugs was started to check the inflow of sub-standard medicines into the country;
- (b) whether a large number of foreign companies have been registered without any inspections of the premises as per the Drug & Cosmetic Act; and
- (c) if so, the steps taken by the Government to ensure that these companies follow the WHO GMP norms and not supply sub-standard drugs?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a): Yes Sir. Under the New system of registration of import of drugs in the country, which came into force 1st April, 2003 no drug can be imported in the country without manufacturing site registration and import licence in Form 10 under the provisions of Drugs & Cosmetics Rules.

(b) and (c) : Inspection of overseas manufacturing sites is not a mandatory criteria for registration of import of drugs. Presently, such imported drugs, which have been in use in the country for considerable period any are duly approved have been registered, provided all formalities prescribed in the Drugs and Cosmetics Rules are complied with. The applicants are required to submit regulatory status of the drug, free sale certificate and GMP certificate in WHO format or certificate of pharmaceutical product (CPP), issued by regulatory authority of the country of origin and Free sale approval issued by the regulatory authorities of other major countries.

At the time of import of the drug the Custom Authorities forwards the bill of entry or any application relating to the consignment to the Port Officer of Central Drugs Standards Control Organisation(CDSCO) at Ports and Airports, prior to import, who check the documents and test the samples at Government or approved testing laboratories. Drugs are cleared for use if they meet the required parameters.